

**UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC**

FSIS DIRECTIVE	6420.1	12-17-98
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**LIVESTOCK POST-MORTEM INSPECTION ACTIVITIES-ENFORCING THE
ZERO TOLERANCES FOR FECAL MATERIAL, INGESTA, AND ILK**

PART ONE--GENERAL

I. PURPOSE

FSIS enforces "zero tolerance" standards for contamination from viscera and mammary glands on carcasses and carcass parts through post-mortem inspection activities at establishments that slaughter livestock. The focus of these activities is contamination with fecal material, ingesta, and milk.

These zero tolerances are food safety standards that also are reflected in FSIS's regulatory requirements. Among other things, the regulations require that establishments handle carcasses, and parts thereof, in a sanitary manner to prevent contamination with fecal material, bile, or foreign matter and that they promptly remove contamination, if it does occur, in a manner satisfactory to the inspector (§ 310.18(a); see also § 308.16(c)). The regulations also require that establishments remove lactating mammary glands without opening the milk ducts or sinuses and the removal and condemnation of contaminated carcass parts, if contact with objectionable material does occur (§ 310.17(a)).

In November 1997, FSIS published a Federal Register notice to assure that as they prepare to comply with the regulations on hazard analysis and critical control point (HACCP) systems (9 CFR part 417), establishment owners and operators are aware of FSIS's position that fecal material is a vehicle for microbial pathogens, and microbiological contamination is a food safety hazard that is reasonably likely to occur in the slaughter production process (62 FR 63254, November 28, 1997). Currently available information also supports treating ingesta and milk as vehicles for microbial pathogens.

This directive updates and supplements previous instructions to inspection program personnel regarding verification of an establishment's procedures for

preventing the contamination of livestock carcasses with fecal material, ingesta, or milk and should such contamination occur, ensuring its removal.

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II. CANCELLATION AND ISSUANCE

This directive replaces the interim guidelines that the Deputy Administrator, Inspection Operations, issued on December 9, 1993, to augment FSIS's zero tolerance policy for fecal, ingesta, and milk contamination in cattle (Interim Guidelines - Immediate Actions on Cattle Clean Meat Program).

III. REASON FOR ISSUANCE

FSIS is issuing this directive to update, and for livestock species other than cattle, supplement the instructions for applying the zero tolerances for fecal, ingesta, and milk contamination in all slaughter establishments (Part Two) and to provide instructions that are appropriate for establishments which are subject to the HACCP system regulations (Part Four) as well as instructions for those to which the HACCP system regulations do not yet apply (Part Three). The HACCP system regulations do not change post-mortem inspection. However, when they apply, somewhat different instructions are needed in order to integrate post-mortem inspection activities with FSIS procedures to verify compliance with regulatory requirements.

The HACCP system regulations apply in official establishments as of the following dates:

January 26, 1998, in an establishment with 500 or more employees ("large establishment");

January 25, 1999, in an establishment with 10 or more but fewer than 500 employees (unless the establishment has annual sales of less than \$2.5 million) ("smaller establishment"); and January 25, 2000, in an establishment with fewer than 10 employees or annual sales of less than \$2.5 million ("very small establishment").

IV. REFERENCES

Regulations: §§ 307.2(g) and (m), 308.16(c), 310.1, 310.3, 310.17, 310.18, 312.6(a), 318.2(b) and (d), and 318.4(b); part 417

V. TERMINOLOGY

IIC-- the inspector in charge

PBIS--the performance-based inspection system

VI. ADDITIONAL INFORMATION

A. Establishment Responsibilities

An official establishment is responsible for assuring that its operations and procedures comply with regulatory requirements, including sanitary dressing and production practices to ensure that livestock products are not adulterated or misbranded. To fulfill its responsibilities, the establishment must control its processes so that (among other things) carcasses are free of fecal material, ingesta, and milk, as required by §§ 310.17(a) and 310.18(a). (See also §§ 307.2(g) and (m), 310.3, and 318.4(b).)

In an establishment not yet subject to part 417 of the regulations, the establishment is responsible for taking corrective action and instituting measures to prevent future noncompliance, as explained in FSIS Directive 8820.1. Under part 417, a HACCP plan must include, as appropriate, critical control points that are designed to control identified food safety hazards (§ 417.2(c)(2)). Because fecal material is a vehicle for pathogens, and microbiological contamination is a food safety hazard that is reasonably likely to occur in the slaughter production process, a slaughter establishment that is subject to part 417 of the regulations must adopt controls that it can demonstrate are effective in reducing the occurrence of pathogens, including controls that prevent the fecal contamination of carcasses.

- o “Critical control points to eliminate contamination with visible fecal material are predictable and essential components of all slaughter establishments' HACCP plans.

- o “Initial validation of a HACCP plan for slaughter and monitoring thereunder, as verified and documented in establishment records, must demonstrate the effective operation of the plan's controls on a continuing basis.”

(§§ 417.2(a)-(c), 417.3(a), 417.4, and 417.5. See 62 FR 63255.)

Part 417 also requires that a HACCP plan specify the critical limits (maximum and minimum values) to be met at the critical control points and that, at a minimum,

these limits be designed to ensure that requirements in FSIS's regulations pertaining to the specific process or product are met (§§ 417.1 and 417.2(c)(3)). As noted above, FSIS regulations include contamination prevention and removal requirements.

B. Inspection Program Responsibilities

1. This directive does not change the disposition of livestock carcasses and carcass parts during carcass examination at the post-mortem rail inspection station. It provides additional instructions on decisionmaking involving noncompliance with regulatory requirements in slaughter establishments (part 310; see also §§ 312.6(a) and 318.2(b) and (d)).
2. IIC's and other off-line inspection program personnel verify a slaughter establishment's implementation of sanitary dressing procedures

PART TWO--ALL SLAUGHTER ESTABLISHMENTS

I. IDENTIFICATION OF CONTAMINANTS

In determining whether an establishment has prevented the contamination of or removed contaminants from carcasses, inspection program personnel assigned zero tolerance verification activities must properly identify contamination with feces, ingesta, or milk.

A. Feces and Ingesta

Inspection program personnel are to identify foreign material as feces or ingesta based on two factors: color and texture.

- o The color of fecal or ingesta contamination is yellow, green, or brown, in the case of cattle; tan to dark brown, in the case of swine; and brown to black, in the case of sheep and goats.

- o Fecal or ingesta contamination has a fibrous or plant-like texture. Sheep and goat feces and ingesta may be tarry. Swine feces and ingesta may include identifiable grain particles. Inspection program personnel should identify foreign material as feces or ingesta only when they are able to identify **both** color and texture, as described above. In and of itself, size is unimportant in identifying fecal or ingesta contamination. However, as size decreases, color and texture become more difficult to discern.

B. Milk

Inspection program personnel are to identify foreign material as milk based on two factors: color and consistency.

- o The color of milk ranges from clear to white to light yellow.

- o The consistency of milk ranges from watery to ropy or curdy.

Milk, if present, tends to be found on the midline, during or after removal of mammary glands (udder).

II. CONTAMINATION CHECKS

A. General

In each establishment slaughtering livestock, inspection program activities include checks to determine that an establishment is not presenting carcasses that are contaminated with fecal material, ingesta, or milk. (See §§ 307.2(g), 310.3, 310.17(a), 310.18(a), and 318.2(b) and (d))

B. Activities

1. On-line inspection program personnel verify compliance of removal of contamination during examination of such carcass at the post-mortem rail inspection station. When these on-line inspection program personnel find feces, ingesta, or milk, the establishment reexamines and reworks the entire carcass (trimming all contamination).
 - a. On-line inspection program personnel are to stop the slaughter line for carcass reexamination and rework by the establishment unless--
 - o the establishment has elected to provide a rail-out loop to rail contaminated carcasses off-line for reexamination, trimming, and positioning back on the line for final inspection, and
 - o the IIC has not determined that the establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses.
 - b. On-line inspection program personnel who also retain a carcass for veterinary disposition are not to authorize establishment trimming until after disposition by a veterinary medical officer.
 - c. On-line inspection program personnel are to notify the IIC or, if unavailable, other off-line inspection program personnel when they believe that--
 - o an establishment's rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses, or
 - o an establishment's slaughter or dressing processes are not under control (for example, when repeated presentation of contaminated carcasses for post-mortem inspection at the rail inspection station indicates failure to control dressing processes).
2. IIC's and other off-line inspection program personnel verify the adequacy of establishment procedures to ensure compliance with zero tolerances for fecal, ingesta, or milk contamination, **when notified by on-line inspection program personnel of an apparent problem or scheduled by PBIS**. When verifying establishment procedures, off-line inspection program personnel are to select carcass units at the post-mortem rail inspection station for examination on-line, at or after the post-mortem rail inspection station. (This inspection should occur before the final wash. In situations where this is difficult, such as those related to worker safety, the IIC should develop appropriate procedures with plant management in order for this inspection to be properly conducted).

- a. Based on the expected slaughter volume for that day (number of animals), determine the number of carcass units to be examined, using the following table. If carcasses are split, each half carcass is $\frac{1}{2}$ of a carcass unit (so select two times as many half-carcasses).

<u>number of animals</u>	<u>number of carcass units</u>
100 or fewer	2
101 to 250	4
251 to 500	7
more than 500	11

- b. Select the carcass units randomly (using an established FSIS method).
- c. Examine the selected carcass units using the technique that inspection program personnel use at the post-mortem rail inspection station. For results and follow-up, see Part Three (at establishments that are not yet subject to the HACCP system regulations) or Part Four (at establishments that are subject to the HACCP system regulations).

PART THREE--SLAUGHTER ESTABLISHMENTS NOT SUBJECT TO THE HACCP SYSTEM REGULATIONS

I. REFERENCES

FSIS Directive 8800.2
FSIS Directive 8820.1
FSIS Form 8800-2

II. TERMINOLOGY

DCG-- Deficiency Classification Guide	(Attachment 1 to FSIS
Directive 8820.1, Rev. 2)	ISG--
Inspection System Guide (FSIS Directive 5400.1)	PDR--
Process Deficiency Record, FSIS Form 8820-2	(Attachment 2 to FSIS
Directive 8820.1)	

III. VERIFICATION RESULTS AND FOLLOW-UP

A. General

The ISG addresses checks for compliance with § 310.18 in task 03E01a1/a2 and checks for compliance with § 310.17 in task 03E03a2 under off-line slaughter, sanitary dressing procedures (Process 03E). IIC's and other off-line inspection program personnel are to use these task codes to document verification of the adequacy of establishment procedures to ensure compliance with requirements to prevent fecal material, ingesta, or milk contamination and, should it occur, ensure its removal by the post-mortem rail inspection station.

B. Results

1. No noncompliance findings

Inspection program personnel who find no feces, ingesta, or milk are to mark the Inspector Assignment Schedule (FSIS Form 8800-2) to indicate performance of the task. (Take no further action.)

2. Noncompliance findings

Inspection program personnel who find any feces, ingesta, or milk are to classify and document the deficiency on a PDR and take other action, as set out below and as appropriate under FSIS Directives 8800.2 and 8820.1.

- a. Immediately notify establishment management verbally of the contamination finding and of the establishment's responsibility for taking immediate corrective and preventive action(s).

- b. Verify the effectiveness of the establishment's immediate corrective action by checking the adequacy of trimming by establishment personnel, as instructed in FSIS Directive 8820.1.
- c. If an IIC finds that, as documented on a series of PDR's, an establishment has failed to take effective corrective and preventive actions and, thus, repeated or recurring noncompliance indicates that the establishment's slaughter and dressing processes are not under control, the IIC should discuss this at the weekly meetings held with establishment management. If the IIC subsequently determines that the multiple, recurring noncompliances which demonstrate the failure of the establishment to implement effective corrective and preventive action warrant a withholding action, he or she shall contact the District Office (DO) and provide all the relevant information for the DO to prepare a letter notifying the establishment of intended enforcement actions.

PART FOUR--SLAUGHTER ESTABLISHMENTS SUBJECT TO THE HACCP SYSTEM REGULATIONS

I. REFERENCES

FSIS Directive 5000.1
FSIS Directive 5400.5

II. TERMINOLOGY

ISP-- inspection system procedure(s), as compiled in the ISP Guide (Attachment 8 to FSIS Directive 5400.5).

NDG-- Noncompliance Determination Guide
(Attachment 7 to FSIS Directive 5400.5)

NR-- Noncompliance Record, FSIS Form 5400.5-3
(Attachment 6 to FSIS Directive 5400.5)

PS-- Procedure Schedule, FSIS Form 5400.5-3A
(Attachment 4 to FSIS Directive 5400.5)

III. VERIFICATION RESULTS AND FOLLOW-UP

A. General

The ISP Guide addresses verification of compliance with zero tolerance requirements for fecal material as a component of ISP procedure 03J01 and 03J02. This includes limits and procedures for off-line inspection personnel to verify that carcasses are not contaminated with fecal material, ingesta, or milk by the post-mortem rail inspection station.

1. Inspection program personnel are to document the performance, and follow-up on the results, of their verification of establishment activities to verify compliance with §§ 310.17(a), 310.18(a), and Part 417 along with other features of ISP procedure 03J01. (i.e., treat the results as the results of a single procedure on the PS and, when applicable, the NR.)
2. If inspection program personnel find feces, ingesta or milk while performing ISP procedure 03J02, they are to complete that procedure (not perform another one) and include the noncompliance with § 310.18(a) or § 310.17(a) in their findings.

C. Results

1. No noncompliance findings

Inspection program personnel who find no feces, ingesta, or milk are to mark the PS to indicate performance after completing all components of the procedure.

2. Noncompliance findings

Inspection program personnel who find feces, ingesta, or milk are to document and follow-up on the noncompliance with § 310.18(a) or § 310.17(a), as instructed in FSIS Directive 5400.5 and as follows.

- a. The "monitoring" trend indicator applies to this noncompliance finding. (See the NDG for which trend indicator to use when other noncompliance is found during performance of ISP procedure 03J01.) FSIS also will utilize findings of § 310.18(a) noncompliance in considering establishment performance for purposes of the frequency and timing of FSIS testing for Salmonella (§ 310.25(b)(2)).
- b. Immediately notify establishment management verbally of the contamination finding and the applicability of § 417.3 (the requirements for corrective action).
- c. Perform ISP procedure 03J02. Determine whether the establishment takes corrective action, as required by § 417.3. Focus on the lot, at slaughter, or the shipment, thereafter, in which one or more contaminated carcasses or carcass parts were found.

As to the § 310.17(a) and § 310.18(a) component of the procedure, the objective is to determine whether sanitary dressing critical control points (as monitored to ensure associated critical limits are met) are adequate to prevent noncompliance with the zero tolerance standards. The HACCP plan, in operation, must prevent the presentation of contaminated livestock carcasses for post-mortem inspection, as verified and documented by the establishment (§§ 417.2(c), 417.4(a), and 417.5(a), (b), and (c)). (See FSIS Directive 5000.1, Part Two, Paragraphs III.B. and III.C. and FSIS Notice 12-98)

/s/ Margaret O'K. Glavin
Deputy Administrator Office of
Policy, Program Development and Evaluation